REMARKS

Claims 1, 3, 4, 6, 7, and 85 are pending in the application. Claims 9-79 have been cancelled as drawn to a nonelected invention. Claims 2, 5, 8, and 80-84 have also been cancelled. Claims 1, 3, 4, 6, and 7 have been amended herein. New claim 85 has been added. The amendments to claims 3, 4, 6, and 7 are supported by the claims as originally filed. The amendment to claim 1 is supported by disclosure at page 63, lines 18-25 of the specification. New claim 85 is supported by disclosure,for example at page 34, lines 20-22 of the specification. Thus, no new matter has been added.

Objections and Rejections

Restriction/Election

The Examiner maintains that the elected invention of Group I is subject to a restriction requirement. Specifically, in the Restriction Requirement mailed September 20, 2001, the Examiner states "[f]or an elected invention drawn to a nucleic acid or amino acid sequences, Applicants must further elect a single nucleic acid or amino acid sequence."

In order to expedite prosecution, Applicants have cancelled claims 5 and 84. None of the remaining pending claims recite nucleic acid or amino acid sequences. Therefore, the requirement to elect a single sequence is now moot.

35 U.S.C. § 132

The amendment filed October 4, 2002 has been objected to for introducing new matter into the disclosure. Specifically, the disclosure was amended to incorporate the contents of applications PCT/US99/08794, 60/082,487 and 09/345,217 by reference. The Examiner has acknowledged that the specification as originally filed claimed priority to PCT/US99/08794 and 60/082,487. However, the Examiner asserts that the subject matter of applications PCT/US99/08794, 60/082,487 and 09/345,217 was not incorporated by reference in the specificaiton as originally filed.

Applicants have amended the specification as required to cancel incorporation of the contents of applications PCT/US99/08794, 60/082,487 and 09/345,217 by reference. Therefore, the objection is now moot.

35 U.S.C. § 112, first paragraph

Claims 1-8 and 80-84 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner has acknowledged that the specfication is enabling for "methods for determining a pregnant woman's predisposition to having a low birth weight baby comprising detecting the presence of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 . . . ." OA at page 4. However, the Examiner asserts that the specification does not enable one of ordinary skill in the art to make and use methods to determine a predisposition to an adverse pregnancy outcome by detecting alleles in linkage disequilibrium with IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. Applicants traverse.

Applicants have amended claim 1 to recite a method for determining a female subject's predisposition to having a low birth weight baby by detecting IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. The genotype of a female subject is the same in the presence or absence of pregnancy. In Example 1 of the specification, the genotype of pregnant women was determined in order to provide a measurable parameter (*i.e.* birth weight of babies). Therefore, Applicants submit that claim 1, as amended herein, is fully enabled by the specification as filed. Claims 3, 4, 6, and 7 and new claim 85, each depends, either directly or indirectly from claim 1, and as such necessarily contain all of the limitations of claim 1. Moreover, claims 2, 5, 8, and 80-84 have been cancelled. Thus, this rejection is moot and should be withdrawn.

Claims 1-8 and 80-84 have been rejected under 35 U.S.C. § 112, first paragraph for lack of written description. According to the Examiner, Applicants have not adequately described detecting alleles in linkage disequilibrium with IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 to predict an adverse pregnancy outcome or to predict having a low birth weight baby. As mentioned above, claim 1 has been amended to recite a method for determining a predisposition to having a low birth weight baby by detecting IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. Applicants assert that claim 1, as amended, recites subject matter which is described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time of filing. Claims 3, 4, 6, and 7 and new claim 85, each depends, either directly or indirectly from claim 1, and as such necessarily contain all of the

limitations of claim 1. Moreover, claims 2, 5, 8, and 80-84 have been cancelled. Therefore, this rejection should be withdrawn.

Double Patenting

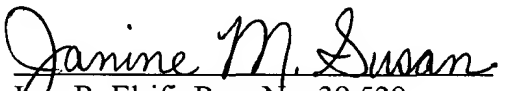
Claims 1-8 and 80-84 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of United States Patent Number 6,268,142.

Once allowable claims are obtained, a terminal disclaimer will be filed. Until such allowable claims are obtained, Applicants respectfully request that this rejection be held in abeyance.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance, and a Notice of Allowance is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



Ivor R. Elrifi, Reg. No. 39,529
Janine M. Susan, Reg. No. 46,119
c/o MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY AND POPEO, P.C.
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

Dated: June 23, 2003